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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BROOKS KUSHMAN P.C.
1000 TOWN CENTER
TWENTY-SECOND FLOOR
SOUTHFIELD, MI 48075

EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,954	JONES, DAVID HUGH	
	Examiner	Art Unit	
	SUZANNE M. NOAKES	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-42* is/are pending in the application.

4a) Of the above claim(s) *22 and 24-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/09/2007 & 07/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-21 and 23 in the reply filed on 04 March 2008 is acknowledged. Claims 22 and 24-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter.

Status of the Claims

2. It is noted that claim 23 has been cancelled. Thus, claims 1-22 and 24-42 are pending and claims 1-21 are subject to examination on the merits.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 28 July 2006 and 09 July 2007 have been considered by the examiner. See initialed and signed PTO-1449's.

Specification

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in

upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

5. Claims 6 and 14 are objected to because of the following informalities.

Claim 6 recites the acronym "EDTA". In the first instance where an acronym is used in an independent claim, said acronym should be spelled out in full, followed by the abbreviation in parenthesis.

Claim 14 is objected to because it used the acronym Con A for the protein concanavalin A. "Con A" should be spelled out in its first occurrence in the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 – 2nd paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a) expressing a recombinant glucose binding protein in a non-plant host cell, b) producing a lysate containing said glucose binding protein wherein said lysate has a reduced glycogen content and c) recovering said glucose binding protein.

8. Claims 2-13 are deemed indefinite because it is unclear in claim 2 what the treating step does or accomplishes. It is noted that this “treatment” step does not produce any sort of result, e.g. is the protein insoluble and glucose soluble because the treatment of the lysate with the buffer or as a consequence of the expression in a non-plant host cell. And if the later, what is the point of “treating a lysate” with said buffer, e.g. what does the treatment actually do? e.g. does it remove residual glycogen? Or something else altogether?

9. Claim 14 recites the limitation "further comprising the step of removing any glycogen-ConA complex formed" in reference to claim 1. There is insufficient antecedent basis for this limitation in the claim because claim 1 does not describe ConA-glycogen complexes.

Claim Rejections - 35 USC § 112 – 1st paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for isolating recombinant plant Concanavalin A from a non-plant host cell comprising: a) expressing ConA in a glycogen deficient host cell or a host cell grown in the absence of glucose as the carbon source; b) lysing the host cell of a) and removing residual glycogen of the lysate by performing the lysing and washing steps in a borate-EDTA buffer and c) recovering ConA, is not enabling for a method of obtaining all recombinant glucose binding proteins expressed in non-plant host cells simply by reducing the glycogen content of the cell lysate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single,

simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to methods of obtaining a recombinant glucose binding protein which is expressed in a non-plant host cell by reducing the glycogen content (claim 1). It is noted that a few steps in the method seemingly have been omitted (see 112 2nd rejection above), however, the claims are interpreted to comprise these steps. Further claim limitations specify that the lysate is treated with a buffer wherein glycogen is soluble but wherein said protein is insoluble (claim 2) and that this buffer can be CHES or Borate (claims 9-11) which require certain pH's and ionic strengths (claims 4 and 12). However, it is noted that this "treatment" step does not produce any sort of result, e.g. is the protein insoluble and glucose soluble because the buffer or as a consequence of the expression in a non-plant host cell. Furthermore, what is the end point of the treatment? E.g. what does the treatment actually do? – (see 112 2nd rejection above). However, it is noted that not all glucose binding proteins expressed in non-plant host cells are insoluble simply by expressing them in non-plant host cells. And not all glucose binding proteins will be insoluble in a buffer yet have glucose and other impurities soluble at the same time as this will depend on the glucose binding

proteins isoelectric point. Thus, some glucose binding proteins may be soluble in buffers at pH 8.5-9.5 (as stated in claim 4 and 12). The direction and guidance in the specification is limited to a Concanavalin A protein isolated from Jackbeans , wherein the methodology of producing said Jackbean consists of that as shown in Figure 13 and wherein the host cell is *E. coli*. Many of the problems encountered with producing this eukaryotic protein may only be encountered when produced recombinantly in prokaryotic host cells wherein the glycogen content is exceptionally high, especially when supplemented with glucose as a carbon source. However, the unique problem of concanavalin A precipitating due to the binding of glycogen does not necessarily extend to all other glucose binding proteins and thus reducing the glycogen content of the host cell or of a lysate may have no effect at all on obtaining said protein. All of the working examples in the specification are drawn to concanvalin A from Jackbeans and the prior art does not detail or suggest that the problem of glucose binding proteins precipitating upon binding glycogen is a problem; rather the prior art seems to suggest that it is rather a problem of producing eukaryotic proteins in a prokaryotic host (see, for example, Stubbs et al., JBC, 1995, 261(14):6141-6144 wherein mutant pea lectins were produced which were expressed in *E. coli* with no difficulties or aggregation at all). The predictability of whether or not this particular methodology would work for all other glucose binding proteins is low and a skilled artisan would necessarily have to endure needless experimentation, despite the high level of skill in the art, to ascertain which glucose binding proteins work in the method and which do not. As such, the scope of the claims exceed that which is deemed enabled.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-3, 14-16, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Dincturk et al. (J. Biosci., 2001, 26(5):635-40 – cited on IDS from 09 July 2007).

The instant specification states that glycogen synthesized in bacterial cells forms a complex with active conconavalin A (ConA) – (see p. 7, last paragraph, to p. 8, 1st paragraph) and that *E. coli* produces significant amounts of glycogen, especially when the growth medium is supplemented with the carbon source glucose.

Dincturk et al. teach the expression of recombinant ConA in *E. coli* cultured in LB medium (e.g. tryptone, yeast extract, NaCl, pH 7.0) (see p. 635, section 2.1). The cultures were centrifuged and then lysed in 120 mM Tris-HCl p.H 6.8, 100 mM DTT, 3% SDS, 1-2& bromophenol blue and 20% glycerol and sonicated. The lysate was boiled and centrifuged. The protein ConA appeared in the pellet and was thus removed from the lysate (see p. 636, Section 2.2). As it is noted above, ConA forms a complex with glycogen, and thus when Dincturk et al. teach removing the precipitated ConA by centrifuging the cell lysate, inherently the glycogen-ConA complex is thus removed as well. Therefore, the glycogen content of the cell lysate is also being reduced at the same time. Since claim 1 simply states the method of obtaining a recombinant glucose

binding protein is achieved by reducing the glycogen content of a cell lysate, the teachings of Dincturk et al. meets this limitation. With regard to claims 2 and 3, the claims do not require that the protein be insoluble as a direct consequence of "treating" the lysate with the buffer. Thus, the fact that protein is insoluble already (whether it has to do to the fact that glycogen complexes to it and makes it insoluble or other factors that make expressing eukaryotic proteins in prokaryotes difficult and form inclusion bodies, is inconsequential), the excess glycogen and at least some of the other impurities would be soluble in the buffer as taught by Dincturk et al.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Suzanne M. Noakes/
Patent Examiner, Art Unit 1656
06 June 2008